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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/753,061 | 01/08/2004 | Johan Boelens | 17601.43 | 2469 |

57360 7590 10/01/2009

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| EXAMINER | |
|---|---|
| ROGERS, MARTIN K | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1791 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 10/01/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/753,061 | BOELENS ET AL. | |
| | Examiner | Art Unit | |
| | MARTIN ROGERS | 1791 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6,9-12,15,16 and 21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 9-12, 15-16, 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 9, 10, 21-26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (EP 1132059 already of record) in view of Gurbel et al (USP 5295959), Spreigl et al. (USP 6161029), Klumb et al. (USP 6238430), Harada et al. (USP 5242451), and Wiktor (USP 4886062).

In regards to claims 1, 4 and 23, Johnson discloses folding a balloon into a number of longitudinal pleats, either manually or by machine ([0031]), placing the balloon into a mold, and pressurizing and heating the mold ([0035] and [0036]) to create protrusions in any area where the balloon is not compressed with a phantom stent ([0040]). The phantom stent is later removed and replaced with the actual stent after the shaping operation. Although Johnson does not explicitly disclose positioning a stent defining a plurality of apertures around the balloon such that the protrusions extend through the plurality of apertures defined by the stent, it is disclosed that Johnson envisions using a multitude of currently available stents ([0020]), suggesting to one of

ordinary skill in the art that any well known stent geometry for use with an inflatable balloon catheter would be suitable for the invention of Johnson.

The use of stents with a plurality of apertures between adjacently spaced loops in the stents are well known in the art. Evidence for this is provided by Spreigl (Figure 6: 130), Klumb (Figure 2E: 48), Harada (Figure 5b: 10), and Wiktor (Figure 6: 1). It would therefore be obvious to one of ordinary skill in the art use a stent with spaced coils (as disclosed by the cited examples) with the invention of Johnson for the benefit of these being well known stents in the art for use with a balloon catheter. Johnson discloses that any area of the balloon not compressed by the phantom stent will protrude (Figures 3 and 7). In order to achieve the position-retention advantages disclosed by Johnson ([0040]), which are achieved by molding the balloon into conformity with a phantom stent ([0041]), the combination of references will result in protrusions forming between the loops of the phantom stent during the molding step. The helical shape of the cited stents will require a wrapped phantom stent in order to achieve a spiral-shaped groove in the balloon. It is therefore the examiner's position that these protrusions will then extend through spaces in the actual stent.

In any event, Gurbel suggests to one of ordinary skill in the art that by providing the exterior of a balloon with recesses that match the coils of a stent, the stent is held more securely during surgery and the outer profile of the catheter is made for compact and smooth (Column 3, lines 3-6). It is stated by Gurbel that these recesses are created with the use of a wrapped phantom stent during the molding step (Column 6, lines 32-36). One applying the teachings of Gurbel to the catheter molding step of the previous

combination would therefore find it obvious to create recesses in the catheter balloon (as disclosed by Gurbel) with protrusions that are specifically adapted to extend through the spaces in the stent in order to securely hold the stents of the above combination as well as reduce the profile of the catheter.

In regards to claims 2 and 24, Johnson further discloses applying heat ([0037]) during the balloon molding.

In regards to claims 3 and 9, Johnson further discloses the use of PTFE.

In regards to claims 10 and 25, it is generally well known in the art to fold balloons using the actual stent, or by hand, or by using a folding machine. These methods are known equivalents for forming a balloon.

In regards to claims 21 and 26 Harada further discloses that one well known type of stent has a flat-band shape (Figure 5), therefore requiring a phantom stent that is also a flat band.

In regards to claim 22 and 27, Spreigl further discloses a catheter with a thread-like cross-section (Figure 6) and Klumb also discloses a thread-like stent (Figure 2), therefore requiring a phantom stent in the form of a filament or thread for the process of Johnson.

Claims 5, 6, 11, 12, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the previous combination of Johnson et al. (EP 1132059 already of record) in view of Gurbel et al (USP 5295959), Spreigl et al. (USP 6161029), Klumb et al. (USP 6238430), Harada et al. (USP 5242451), and Wiktor (USP 4886062) as applied to claims 1, 4 and 23 above, and further in view of Blackshear Jr. et al. (USP 5308356).

In regards to claims 5, 11 and 15, Johnson is silent as to the method used to form the balloon catheter, suggesting to one of ordinary skill in the art that any well known method for making such a balloon catheter would be suitable for the invention.

Blackshear discloses that one well known method of making a balloon catheter is to introduce a tube into a mold and inflate in the tube into the shape of the balloon (Column 6, lines 41-46). In order to use the product, it must inherently be removed from the mold after being formed.

In regards to claims 6, 12 and 16, Johnson further discloses that the balloon be attached to a catheter ([0032] and Figure 2: 18).

***Response to Arguments***

Applicant's arguments filed 8/10/2009 have been fully considered but they are not persuasive.

In regards to claims 1-4 and 9, Applicant argues on page 7 of the remarks that because Johnson discloses that the balloon is formed with "a pair of round annular shoulders immediately adjacent the proximal and distal ends of the stent," the language of the claim was not met because Applicant explicitly required "leaving uncompressed portions of the balloon between the spaced apart loops of the member wrapped around the balloon." The examiner respectfully submits that Applicant misunderstood the original rejection. Although it is true that the specific embodiment shown in the figures of Johnson do not have the balloon geometry required by Applicant, this is disclosed by Johnson to only be one exemplary embodiment of the invention. As stated by the examiner in the original rejection, Johnson discloses that helical stents are also well known in the art and that the phantom stent can have a spiral configuration ([0040]-[0041]). Therefore, it was the examiner's position that if the use of the spiral-shaped phantom stent did not inherently have spaces which caused uncompressed portions of the balloon to form protrusions, then use of helical stents which do have spaces formed between adjacent loops is well known in the art and would have to one of ordinary skill in the art to use with the invention of Johnson.

Applicant further argues on page 8 of the remarks that because Johnson discloses surrounding the stent or phantom stent with a tube (58) during forming, it is not possible for protrusions to extend through any spaces which may be present in the stent of phantom stent at the time of forming. The examiner respectfully disagrees with this assertion. If local areas of the balloon were inflated through openings in the stent or

phantom stent until they reached the inner circumference of tube 58, then these protrusions would certainly be considered to be extending through the openings of the stent or phantom stent.

In regards to claims 5-8 and 11-15, Applicant requests on page 8 of the remarks that prior art be cited that provides evidence that folding by a machine or folding by hand are obvious alternatives for pleating a balloon. [0032] of Johnson provides evidence that folding by hand or folding with a machine for obvious alternatives for creating pleats in the catheter balloon.

In regards to claims 10 and 25, Applicant requests on page 9 of the remarks that the examiner provide evidence that the use of a stent to fold a balloon is a well known obvious alternative to folding the balloon by itself with a machine or by hand. Davis discloses that folding a balloon by wrapping a member around a balloon is well known in the art (Column 2, lines 53-56) and serves the same function that is performed by the machine or hand folding or Johnson (i.e. to form pleats in the balloon). Mostenbocker discloses that it is well known in the art to use a device which crimps a stent around a balloon to also fold just the balloon ([0075]).

***Conclusion***

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARTIN ROGERS whose telephone number is 571-270-7002. The examiner can normally be reached on Monday through Thursday, 7:30 to 5:00, and every other Friday, 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MR

/Christina Johnson/
Supervisory Patent Examiner, Art Unit 1791